IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellants:	**Robert C. Beck**	Examiner:	**Matthew F. DeSanto**
Serial No.:	**09/995,303**	Group Art Unit:	**3763**
Filing Date:	**November 27, 2001**	Docket No.:	**2446**
Title	**Interventional Device**		

Date of Deposit: 1-3-08
I hereby certify that this paper is being deposited in the United States Postal Service, as first class mail, in an envelope addressed to: Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450

Signature: Mary S. Keller
Printed Name: Mary S. Keller

BRIEF ON APPEAL

Mail Stop AF
Commissioner for Patents
Alexandria, VA 22313

Sir:

This Brief on Appeal is filed pursuant to the Notice of Appeal filed 05/03/07 and is an appeal from the Office Action mailed from the U.S. Patent and Trademark Office on 01/03/07. The fee for filing an appeal brief was transmitted with the notice of appeal. The balance of this appeal is set forth under appropriate headings, as specified by 37. C.F.R. §1.192(c).

I. REAL PARTY IN INTEREST

The real part in interest is Sprite Solutions, 2256 Hendon Avenue, St. Paul, MN 55108, Assignee of the entire right, title and interest in the subject application, by virtue of an Assignment recorded on January 18, 2005 at Reel 016153, Frame 0099. Sprite Solutions has licensed the patent application to Medrad Inc. of Indianola PA.

II. RELATED APPEALS AND INTERFERENCES

Appellant, the undersigned Attorney and Assignee are not aware of any related appeals or interferences that will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIM

Claims 7-9 and 18-24 and 27-30 are pending in the application and they have been finally rejected. A copy of the claims appears in the Appendix of this Brief. These claims were amended in the Amendment filed on 10/05/06. Claims 1-6, 10-17 and 25-26 were canceled.

IV. STATUS OF AMENDMENTS

No Amendment After Final has been filed.

V. SUMMARY OF CLAIMED SUBJECT MATTER

The specification shows in Fig. 1 an injector 12 for injecting fluid from a syringe 14 into an interventional device 10 (catheter). Fluid injected in to the patient is collected at the treatment site in the patient and extracted or recovered though the body 9 of the interventional device coupled to a collection vessel 22. In short the fluid injected into the catheter is ultimately collected along with biologic debris from the treatment site.

Fig. 2 shows a simple embodiment of the invention. The view is of the working end of the device 10. In terms of the claims at issue in this appeal, the extraction sheath 27 contains the discharge lumen 20 that is used to collect fluid and debris. In Fig. 2 the Coanda nozzle of the interventional device is shown formed by the conical wall 42 (nubbin) and the gap 40 which cooperate together to turn the fluid 44 through an angle and shoot it toward the open end 36 of the extraction sheath 27.

Fig. 13-17 show the "angioplasty/stent placement balloon" embodiments addressed in the claims on appeal.

Independent claim 7 adds an angioplasty balloon to the structure of Fig. 2 and independent claim 28 adds a stent placement balloon 77 (Fig. 13) to the structure of Fig. 2. In all other respects the two independent claims are essentially the same. The method of independent claim 7 starts with the passage of the extraction sheath and the interventional device to the treatment site. Next fluid is injected though the gap 79 (Fig. 13) next to the "wall" formed in Fig. 13 by nubbin 76. The Coanda effect occurs in this circumstance and the primary injected jet turns through an angle shown in Fig. 14 as flow 74, or in Fig. 2 as flow 44. The "whereby clause" results form the operation of the Coanda effect promoting the flow into the exhaust sheath.

Please note that other structural features seen in Fig. 13-17 show how the nubbin can be made as a balloon rather than as a rigid structure seen in the remaining figures. This has not been the subject of claims.

By way of argument kindly note that the use of the Coanda effect to direct flow is not shown in the references applied during prosecution and that the use of the Coanda nozzle along with an angioplasty or stent placement balloon is not found in the catheter art.

VI. GROUNDS OF REJECTION TTO BE REVIEWED ON APPEAL

The one issue presented for review is whether the claims are anticipated under 35 U.S.C. §102(e) by the Nash et al. reference (USPN 6,524,323) and under §102(b) by the Fischell et al. reference (USPN 5,100,425).

VII. GROUPING OF CLAIMS AND ARGUMENT

With respect to the arguments on appeal all of the claims stand or fall together as a group.

A. With respect to the rejection of claims 7-9, 18-24 and 27-30 under 35 U.S.C. §102(e) over Nash 6,080,170. Nash fails to show the "gap projecting said fluid jet in an initial direction away from said wall adjacent said gap, said wall serving to restrict entrainment of fluid by said primary fluid flow, thereby creating a pressure difference across said primary fluid jet flow such that said primary fluid flow turns through an angle away from said initial direction away from said wall and turns toward said wall thereby exhibiting the Coanda effect". The method of the claim requires turning fluid using the Coanda effect and that limitation is not present in the Nash reference.

B. With respect to Claims 7-9, 18-24 and 27-30 are rejected under 35 U.S.C. §102(b) under Fischell 5,100,425. Like Nash, Fischell is deficient in the sense that it does not teach the use of a Coanda effect geometry to guide fluid, when carrying out the method of the invention.

C. The method of the claims calls for structures not found in the references (Coanda nozzle claim 7 and claim 28; and stent deployment balloon claim 28). The method calls for relative motions between physical elements not found in the references. Neither Nash nor Fischell shows the use of an angioplasty therapy balloon (claim 7) or a stent deployment balloon (claim 28) in combination with the method of fluid injection and debris recovery called for by the claims. Applicant respectfully asserts that these claims are not anticipated by the references. Applicant requests reversal of the Examiner's decision on these grounds.

EVIDENCE APPENDIX

NONE

RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,
SPRITE SOLUTIONS
By its attorneys:

Date: 1/3/08

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CLAIMS

Claims 1-6 (Canceled)

7. (Previously Amended) A method of removing particulate debris from a vessel using a catheter assembly the method comprising:

inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel, said sheath not having an occlusion balloon thereon such that said sheath partially blocks the vessel but allowing some blood flow in the vessel;

inserting and advancing an interventional device to a treatment location said interventional device of type having;

an elongate body enclosing a fluid supply lumen and a angioplasty therapy inflation lumen;

an angioplasty therapy balloon for delivering angioplasty treatment located near the distal tip of said elongate body;

said elongate body having a central axis extending in the direction of the therapy balloon;

a gap communicating with said fluid supply lumen for introducing a primary fluid jet flow in said vessel, said gap located distal of said therapy balloon, said gap projecting said fluid jet in an initial direction away from the central axis of the interventional device said wall located immediately adjacent said gap, and forming an annular surface next to the gap on the interventional device;

said wall serving to restrict entrainment of fluid by said primary fluid flow, thereby creating a pressure difference across said primary fluid jet flow such that said primary fluid flow turns through an angle away from said initial direction away from said wall and turns toward said wall thereby exhibiting the Coanda effect and thereby;

promoting retrograde flow into said discharge lumen.

8. (Previously presented) The method of claim 18 wherein said moving step begins near said occlusion and ends after the interventional device enters the delivery sheath.

9. (Previously presented) The method of claim 7 wherein said fluid is injected at a first injection pressure above the blood pressure in the vessel and the injected fluid pressure drop to a second exhaust pressure in said delivery catheter where said exhaust pressure is above said blood pressure, establishing a pressure gradient in said discharge lumen and promoting flow from said gap to said discharge lumen.

Claims 10-17 (Canceled)

18. (Previously presented) The method of claim 7 wherein said injection is carried out while moving said interventional device in said vessel with respect to said delivery sheath.

19. (Previously presented) The method of claim 7 wherein said discharge lumen is coupled to a syringe collection chamber.

20 (Previously presented) The method of claim 7 wherein said discharge lumen is coupled to a syringe vacuum chamber.

21. (Previously presented) The method of claim 7 wherein said primary fluid is supplied by a supply syringe chamber.

22. (Previously presented) The method of claim 21 wherein the fluid supplied is a thrombolytic.

23. (Previously presented) The method of claim 21 wherein the fluid supplied is saline.

24. (Previously presented) The method of claim 21 wherein the fluid supplied is contrast agent.

Claims 25-26 (Canceled)

27. (Previously presented) The method of claim 7 wherein said primary fluid is supplied by a supply syringe chamber and said discharge lumen is coupled to a syringe vacuum chamber, and said supply syringe and vacuum syringe are operated together to couple fluid supply with discharge lumen collection.

28. (Previously Amended) A method of removing particulate debris from a vessel using a catheter assembly the method comprising:

inserting and advancing a sheath having a discharge lumen to a location in the vessel said delivery sheath discharge lumen coupled to a collection vessel; said sheath not having an occlusion balloon thereon such that said sheath partially blocks the vessel but allowing some blood flow in the vessel;

inserting and advancing an interventional device to a treatment location said interventional device of type having;

an elongate body enclosing a fluid supply lumen and a stent delivery inflation lumen;

a stent deployment balloon for delivering stent treatment located near the distal tip of said elongate body;

a gap communicating with said fluid supply lumen for introducing a primary fluid flow in said vessel, said gap located distal of said stent deployment balloon, said gap projecting fluid in an initial direction away from the central axis of the interventional device said wall located immediately adjacent said gap; and forming an annular surface next to the gap on the interventional device;

said wall serving to restrict entrainment of fluid by said primary fluid flow, thereby creating a pressure difference across said primary fluid flow such that said primary fluid flow turns through an angle away from said initial direction of the toward said wall thereby exhibiting the Coanda effect thereby;

promoting retrograde flow into said discharge lumen.

29. (Previously presented) The method of claim 28 further including a suction applied to said sheath lumen to withdraw material from said vessel.

30. (Previously presented) The method of claim 29 further including a suction applied to said sheath lumen to withdraw material from said vessel.